UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Thursday, March 17, 2005

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 56392-RN / Swat 200 9B
DP Barcode: D312656

To: Emily Mitchell, PM 32/ Delores Williams
Regulatory Management Branch
Antimicrobials Division (7510C)

From: Ian Blackwell, Biologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

Through: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

3/17/05

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

Applicant: Caltech Industries, Inc.

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Sodium hypochlorite	0.55
Other Ingredient(s):	99.45
Total:	100.00%

1) BACKGROUND: Caltech Industries, Inc., has submitted a set of seven acute toxicity studies to support the registration of their product, "Swat 200 9B". This submission includes two acute oral toxicity studies. The studies were conducted by Stillmeadow, Inc. The MRID Numbers are 464411-06 through 464411-12.

These studies were initially reviewed by the EPA contractor, DynCorp/ CSC. CTT/PSB/AD conducted a brief secondary review.

2) RECOMMENDATIONS: PSB findings are:

a) The acute oral toxicity studies are acceptable. CTT/PSB looked through both studies and could not determine why the lab or registrant conducted two acute oral toxicity studies on the same lot of product. However, this is not a considered a deficiency. It is just peculiar.
b) The acute dermal toxicity, acute inhalation toxicity, primary eye irritation, primary skin irritation, and dermal sensitization studies are all acceptable.

The acute toxicity profile for File Symbol 56392-RN is currently:

Study	MRID Number	Toxicity Category	Status
Acute Oral Toxicity	464411-06, -07	IV	Acceptable
Acute Dermal Toxicity	464411-08	IV	Acceptable
Acute Inhalation Toxicity	464411-09	IV	Acceptable
Primary Eye Irritation	464411-10	IV	Acceptable
Primary Skin Irritation	464411-11	IV	Acceptable
Dermal Sensitization	464411-12	Nonsensitizer	Acceptable

3) LABELING:

a) The signal word is "Caution".

b) This product is a nonsensitizer and is assigned toxicity category IV for all other acute toxicity and primary irritation studies. Due to the acute toxicity profile of 56392-RN, no precautionary labeling (precautionary statements, First Aid statements) is required for this product.

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§ 81-1, 870.1100)
(UP AND DOWN PROCEDURE)

Product Manager: 32
MRID No.: 464411-06

Reviewer: Ian Blackwell
Study Completion Date: December 15, 2004
Report No.: 8751-04

Testing Laboratory: STILLMEADOW, Inc.
Author: Janice O. Kuhn, Ph.D., DABT

Quality Assurance (40 CFR §160.12): A Quality Assurance statement was included. A statement of Good Laboratory Practice (GLP) compliance was also included stating that the study meets the requirements of 40 CFR Part 160 and 792 and OECD specifications.

Test Material: SWAT 200 9B / Lot # CI-34-51 / clear, colorless liquid
Dosage: Limit Test: 5000 mg/kg (administered as received)

Species: 3 Sprague-Dawley albino rats
Sex: Female; nulliparous and nonpregnant
Age: Young adult (approximately 8 weeks)
Weight: 181 - 196 g (fasted weight on dosing day)
Source: Texas Animal Specialties, Humble, TX
Housing: Temperature Range: 18 - 25 °C
Relative Humidity: 20 - 70 %
Photoperiod: 12-hour light/dark cycle
Acclimation: 5 days

Conclusion:

1. **LD_{50} (mg/kg):** Females **>** 5000 mg/kg

2. **Toxicity Category**: IV **Classification**: Acceptable

Procedure (Deviations from §81-1): Lower values of temperature and humidity of animal housing were below the protocol limits, however, the laboratory states that this deviation did not affect study outcome.

Results: No mortality occurred during the study.

Limit Test - Reported Mortality

Dose Level (mg/kg)	No. Dead / No. Dosed (Females)
5000	0 / 3

Observations: All animals appeared normal and there were no clinical signs of toxicity for the duration of the study. Body weight gain was noted for all animals during the test period.

Gross Necropsy Findings: The gross necropsy conducted at termination of the study revealed no observable abnormalities.

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§ 81-1, 870.1100)
(UP AND DOWN PROCEDURE)

Product Manager: 32
MRID No.: 464411-07

Reviewer: Ian Blackwell
Study Completion Date: December 2, 2004
Report No.: 8567-04

Testing Laboratory: STILLMEADOW, Inc.
Author: Janice O. Kuhn, Ph.D., DABT

Quality Assurance (40 CFR §160.12): A Quality Assurance statement was included stating that an in-life inspection was not done and that the study outcome was not affected. A statement of Good Laboratory Practice (GLP) compliance was also included stating that the study meets the requirements of 40 CFR Part 160 and 792 and OECD specifications. The report included an analysis of the active ingredient.

Test Material: SWAT 200 9B / Lot # CI-34-51 / clear, colorless liquid
Dosage: Limit Test: 5000 mg/kg (administered as received)

Species: 3 Sprague-Dawley albino rats
Sex: Female; nulliparous and nonpregnant
Age: Young adult (approximately 8 weeks)
Weight: 162 - 175 g (fasted weight on dosing day)
Source: Texas Animal Specialties, Humble, TX
Housing: Temperature Range: 20 - 22 °C
Relative Humidity: 55 - 100 %
Photoperiod: 12-hour light/dark cycle
Acclimation: 5 days

Conclusion:

1. LD50 (mg/kg): Females > 5000 mg/kg

2. Toxicity Category: IV Classification: Acceptable

Procedure (Deviations from §81-1): Upper value of humidity of animal housing was above protocol limits, however the laboratory states that this deviation did not affect study outcome. Rationale for initial dose level selection was not provided.

Results: No mortality occurred during the study.

Limit Test - Reported Mortality

Dose Level (mg/kg)	No. Dead / No. Dosed (Females)
5000	0 / 3

Observations: All animals appeared normal for the duration of the study. Body weight gain was noted for all animals during the test period.

Gross Necropsy Findings: The gross necropsy conducted at termination of the study revealed no observable abnormalities.

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (§81-2, 870.1200)
(LIMIT TEST)

Product Manager: 32
MRID No.: 464411-08

Reviewer: Ian Blackwell
Study Completion Date: December 15, 2004
Report No.: 8568-04

Testing Laboratory: STILLMEADOW, Inc.
Author: Janice O. Kuhn, Ph.D., DABT

Quality Assurance (40 CFR §160.12): A Quality Assurance statement was provided. A statement of Good Laboratory Practice (GLP) compliance was also included stating that the study meets the requirements of 40 CFR Part 160 and 792 and OECD specifications.

Test Material: SWAT 200 9B / Lot # CI-34-51 / clear, colorless liquid

Species: New Zealand White Albino rabbits
(5 / sex; females were nulliparous and nonpregnant)
Age: Young Adult (approximately 12 weeks)
Weight : Males: 2.600 - 3.050 kg
Females: 2.300 - 3.000 kg
Source: Nichols Rabbitry Inc., Lumberton, TX
Housing: Temperature Range: 19 - 21 °C
Relative Humidity: 67 - 100 %
Photoperiod: 12-hour light / 12-hour dark cycle
Acclimation: 5 days

Summary:

1. **LD_{50} (mg/kg):** Males > 5050 mg/kg
   Females > 5050 mg/kg
   Combined > 5050 mg/kg

2. **The estimated LD_{50} is** > 5050 mg/kg

3. **Tox. Category:** IV **Classification:** Acceptable

Procedure (Deviations From §81-4): The upper humidity level was above the range specified in the guidelines. The laboratory states, however, that the high humidity deviation did not affect study outcome, and that there were no deviations from the protocol that affected the quality or outcome of the study.

Results: No mortality occurred during the study.

Reported Mortality

DOSAGE (mg/kg)	DEATHS / number tested		
	Males	Females	Total
5050	0 / 5	0 / 5	0 / 10

Observations: All animals exceeded their initial body weight by study termination (Day 14). All animals appeared normal for the duration of the study. There were no signs of dermal irritation in any animals during the study.

Gross necropsy findings: The gross necropsy conducted at termination of the study revealed no observable abnormalities, except discolored lungs in one male and two females.

DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (§81-3, 870.1300)
LIMIT TEST

Product Manager: 32
MRID No.: 464411-09

Reviewer: Ian Blackwell
Study Completion Date: December 10, 2004
Report No.: 8569-04

Testing Laboratory: STILLMEADOW, Inc.
Author: Lori Carter, B.A.

Quality Assurance (40 CFR §160.12): A Quality Assurance Statement was provided. A statement of Good Laboratory Practice (GLP) compliance was also included stating that the study was conducted in compliance with 40 CFR Part 160 and 792 and OECD specifications.

Test Material: SWAT 200 9B / Lot # CI-34-51 / clear, colorless liquid

Species: 10 Sprague-Dawley rats
(5 / sex; females - nulliparous and nonpregnant)
Age: Young adult (approximately 8 weeks)
Weight: Males: 271 - 317 grams on the day after receipt
Females: 199 - 212 grams on the day after receipt
Housing: Temperature Range: 20 - 22 °C
Relative Humidity: 56 - 100 %
Photoperiod: 12-hour light/dark cycle
Acclimation: 5 days
Source: Texas Animal Specialities, Humble, TX

Concentration:

Group	Gravimetric Exposure Concentration (mg/L)	Nominal Concentration (mg/L)
I	2.19	2.61

The exposure was conducted in a 500 L nose-only stainless steel inhalation chamber. The test atmosphere concentration in the breathing zone of the rats was determined once per hour during the four-hour exposure period and nominally at the end of the exposure.

Summary:

1. **LC_{50} (mg/L) 4-hr exposure:** Males > 2.19 mg/L
Females > 2.19 mg/L
Combined >2.19 mg/L
2. **The estimated LC_{50} is > 2.19 mg/L**
3. **MMAD**: 2.5 µm
4. **Tox. Category**: IV **Classification**: Acceptable

Procedure (Deviation From §81-3): The upper level of humidity of animal housing was above the humidity range as set by the guidelines, however, the laboratory states that the high humidity did not affect study outcome. Temperature of exposure chamber during the study was below the protocol parameters. The laboratory states that this did not affect study outcome, and that there were no deviations from the protocol which affected the quality or outcome of the study.

Results:

Reported Mortality

Exposure Concentration (mg/L)	Number of deaths / number tested		
	Males	Females	Combined
2.19	0 / 5	0 / 5	0 / 10

Chamber Atmosphere

Expos. Conc. (mg/m^3)	MMAD (mm)	GSD (mm)	% Particles							
			< 18.4	< 11.0	< 4.4	<2.7	< 1.7	< 1.0	< 0.5	< 0.3
2.19	2.2	4.3	96.55	93.10	55.17	17.24	17.24	17.24	3.45	0.00
	2.8	3.9	97.87	76.60	53.19	12.77	4.26	2.13	0.00	0.00

Chamber Environment During Exposure

Exposure Level	2.19 mg/L
Chamber Volume	500 L
Airflow	195 lpm
Temperature	65 ^oF
Relative Humidity	68 %

Clinical Observations: There were no mortalities during the study. Body weight gain was unaffected by administration of the test substance, except in one female that lost weight between Days 0 and 7. Prominent in-life observations included activity decrease and piloerection in both sexes. Animals were asymptomatic by Day 3.

Gross Necropsy Findings: The gross necropsy conducted on each animal at termination of the study revealed no observable abnormalities.

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (§81-4, 870.2400)

Product Manager: 32
MRID No.: 464411-10

Reviewer: Ian Blackwell
Study Completion Date: December 2, 2004
Report No.: 8570-04

Testing Laboratory: STILLMEADOW, Inc.
Author: Janice O. Kuhn, Ph.D., DABT

Quality Assurance (40 CFR §160.12): A Quality Assurance statement was provided. A statement of Good Laboratory Practice (GLP) compliance was also included stating that the study meets the requirements of 40 CFR Part 160 and 792 and OECD specifications.

Test Material: SWAT 200 9B, Lot # CI-34-51, clear, colorless liquid
Dosage: 0.1 mL - undiluted

Species: New Zealand White rabbits
Sex: 2 Male; 1 Female
Age: Approximately 12 weeks
Source: Nichols Rabbitry Inc., Lumberton, TX
Housing: Temperature Range: 19 - 21°C
Relative Humidity: 73 - 100 %
Photoperiod: 12-hour light / 12-hour dark cycle

Summary:

1. **Toxicity Category**: IV
2. **Classification**: Acceptable

Procedure (Deviations From §81-4): The upper level of humidity of animal housing was above that specified by the guidelines. The laboratory states, however, that the high humidity did not affect the study outcome and that there were no deviations from the protocol which affected the quality or outcome of the study.

The pH of the test substance was determined to be 12.2, however, the test was conducted and the test substance was rated minimally irritating.

Results:
There were no "positive" effects exhibited in any eyes at any time during the study.

Incidence of Irritation

Time Post Instillation	Corneal Opacity	Iritis	Conjunctivitis
1 hour	0 / 3	0 / 3	0 / 3
24 hours	0 / 3	0 / 3	0 / 3
48 hours	0 / 3	0 / 3	0 / 3
72 hours	0 / 3	0 / 3	0 / 3

Individual Ocular Irritation Scores

Observations	Rabbit No.: 7890-M (Male)				Rabbit No.: 7892-M (Male)				Rabbit No.: 7897-F (Female)			
	Hours				Hours				Hours			
	1	24	48	72	1	24	48	72	1	24	48	72
I. Corneal Opacity	+	+	0	0	+	0	0	0	0	0	0	0
II. Iritis	0	0	0	0	0	0	0	0	0	0	0	0
III. Conjunctivae:												
A. Redness	0	0	0	0	1	0	0	0	0	1	0	0
B. Chemosis	0	0	0	0	0	0	0	0	0	0	0	0
C. Discharge	1	0	0	0	1	0	0	0	0	0	0	0

Any corneal involvement or iridic irritation with a score of 1 or more is considered positive. Any conjunctival irritation (redness or chemosis) with a score of 2 or more is considered positive.

DATA REVIEW FOR DERMAL IRRITATION TESTING (§81-5, 870.2500)

Product Manager: 32
MRID No.: 464411-11
Reviewer: Ian Blackwell
Study Completion Date: December 2, 2004
Report No.: 8571-04

Testing Laboratory: STILLMEADOW, Inc.
Author: Janice O. Kuhn, Ph.D., DABT

Quality Assurance (40 CFR §160.12): A Qualtiy Assurance statement was provided. A statement of Good Laboratory Practice (GLP) compliance was also included, stating that the study meets the requirements of 40 CFR Part 160 and 792 and OECD specifications.
Test Material: SWAT 200 9B / Lot # CI-34-51 / clear, colorless liquid
Dosage: 0.5 mL - undiluted

Species: New Zealand White Albino rabbits
Sex: 1 Male; 2 Females
Age: Approximately 12 weeks
Source: Nichols Rabbitry Inc., Lumberton, TX
Housing: Temperature: 18 - 21 □C
Humidity: 77 - 100 %
Photoperiod: 12-hour light / 12-hour dark cycle

Summary:

1. **Toxicity Category**: IV

2. **Classification**: Acceptable

Procedure (Deviations From §81-4): The laboratory states that the high humidity did not affect study outcome and that there were no deviations from the protocol which affected the quality or outcome of the study.

The pH of the test substance was determined to be 12.2, however, the study was conducted and the test material was given a descriptive rating of non-irritating.

Results: Erythema and edema were not observed at any time throughout the study. No other signs of irritation were observed during the study.

Incidence of Irritation

Time after Patch Removal	Erythema	Edema
1 hour	0 / 3	0 / 3
24 hours	0 / 3	0 / 3
48 hours	0 / 3	0 / 3
72 hours	0 / 3	0 / 3

DATA REVIEW FOR DERMAL SENSITIZATION TESTING (§81-6, 870.2600)
MODIFIED BUEHLER METHOD

Product Manager: 32 **Reviewer**: Ian Blackwell
MRID No.: 464411-12 **Study Completion Date**: December 15, 2004
Report No.: 8572-04

Testing Laboratory: STILLMEADOW, Inc.
Author: Janice O. Kuhn, Ph.D., DABT

Quality Assurance (40 CFR §160.12): A Quality Assurance statement was included. A statement of Good Laboratory Practice (GLP) compliance also included stating that the study meets the requirements of 40 CFR Part 160 and 792 and OECD specifications.

Test Material: SWAT 200 9B / Lot # CI-34-51 / clear, colorless liquid
Positive Control Material: 1-chloro-2,4-dinitrobenzene (DNCB)

Species: 34 Hartley-Albino guinea pigs
Sex: 17 Male and 17 Female
Age: Approximately 5 weeks
Weight: Males: 302 - 380 grams
Females: 291 - 364 grams
Source: Charles River Laboratories, Wilmington, MA
Housing: Temperature Range: 20 - 24 °C
Relative Humidity: 26 - 92 %
Photoperiod: 12-hour light / 12-hour dark cycle
Acclimation: 5 days

Method: Modified Buehler Design

Summary:

1. **Based on the results of this study, SWAT 200 9B did not elicit a sensitization reaction in guinea pigs.**

2. **Classification**: Acceptable

Procedure (Deviation From §81-6): The upper temperature level and both the lower and upper levels of relative humidity of animal housing were outside protocol limits. The laboratory states, however, that this did not affect the study outcome and that there were no deviations from the protocol that affected the quality or outcome of the study.

It is not indicated whether the females were nulliparous and nonpregnant.

Procedure:

Preparation and Observation of animals: Males and females were selected for each of two treatment groups. Group I animals (5/sex) served as a naive control group and Group II animals (10/sex) served as the test group. On the day prior to each treatment, the animals were prepared by clipping the back of the trunk free of hair to expose a longitudinal area of at least 8x10 cm on each animal. Individual body weights were recorded on Days 0 and 28. Observations for skin reactions at each test site were made approximately 24 hours after each treatment. In addition, observations for skin reactions were made approximately 48 hours after the first induction treatment and 48 hours after the challenge treatment.

Preliminary Irritation: Two male and two female albino guinea pigs were selected for irritation screening to determine both the maximum dose producing no more than moderate irritation, and the maximum non-irritating dose. Concentrations tested in the screening were 100 % (undiluted), and 75%, 50%, and 25% v/v dilution in deionized water, with each animal receiving 0.4 mL of each concentration at different test sites.

Induction Phase: For each induction treatment, Group II animals were treated by introducing the test substance beneath a 4 ply, 2.5 x 2.5 cm surgical gauze patch. Each gauze patch was placed laterally from the midline of the back on the left front quadrant of the exposure area and secured with a strip of non-irritating adhesive tape. A strip of clear polyethylene film was placed over the patch and securely taped. At the end of the 6-hour exposure period, the wrappings and patches were removed. Group II animals were treated once weekly for three weeks with 0.4 mL of the undiluted test substance. Induction treatments were on Days 1, 8 and 15. The same treatment regimen and test site location was used for all three induction treatments. Group I animals remained untreated during the induction phase of the study.

Challenge Phase: After a 2-week rest period, all animals (Groups I and II) were challenged at a virgin test site with a 0.4 mL application of the undiluted test substance. The dose was applied in a manner identical to the induction treatments, except the test site was placed laterally on the right rear quadrant of the exposure area.

Results: The test substance, SWAT 200 9B Lot CI-24-51, produced no irritation in the naive control animals (Group I) after the single treatment at challenge. The test substance likewise produced no irritation in the test animals (Group II) after the challenge treatment and therefore did not elicit a sensitizing reaction in guinea pigs.

Individual Challenge Data

	Dermal Scores	
	Hours	
	24	48
Test Animals	0 / 20	0 / 20
Naive Control Animals	0 / 10	0 / 10

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§ 81-1, 870.1100)
(UP AND DOWN PROCEDURE)

Product Manager: Robert Brennis
MRID No.: 464411-06

Reviewer: Karen Hicks
Study Completion Date: December 15, 2004
Report No.: 8751-04

Testing Laboratory: STILLMEADOW, Inc.
Author: Janice O. Kuhn, Ph.D., DABT

Quality Assurance (40 CFR §160.12): A Quality Assurance statement was included. A statement of Good Laboratory Practice (GLP) compliance was also included stating that the study meets the requirements of 40 CFR Part 160 and 792 and OECD specifications.

Test Material: SWAT 200 9B / Lot # CI-34-51 / clear, colorless liquid
Dosage: Limit Test: 5000 mg/kg (administered as received)

Species: 3 Sprague-Dawley albino rats
Sex: Female; nulliparous and nonpregnant
Age: Young adult (approximately 8 weeks)
Weight: 181 - 196 g (fasted weight on dosing day)
Source: Texas Animal Specialties, Humble, TX
Housing: Temperature Range: 18 - 25 °C
Relative Humidity: 20 - 70 %
Photoperiod: 12-hour light/dark cycle
Acclimation: 5 days

Conclusion:

1. **LD_{50} (mg/kg):** Females > 5000 mg/kg

2. **Tox. Category**: IV **Classification**:

Procedure (Deviations from §81-1): Lower values of temperature and humidity of animal housing were below the protocol limits, however, the laboratory states that this deviation did not affect study outcome.

Results: No mortality occurred during the study.

Limit Test - Reported Mortality

Dose Level (mg/kg)	No. Dead / No. Dosed (Females)
5000	0 / 3

Observations: All animals appeared normal and there were no clinical signs of toxicity for the duration of the study. Body weight gain was noted for all animals during the test period.

Gross Necropsy Findings: The gross necropsy conducted at termination of the study revealed no observable abnormalities.

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§ 81-1, 870.1100)
(UP AND DOWN PROCEDURE)

Product Manager: Robert Brennis
MRID No.: 464411-07

Reviewer: Karen Hicks
Study Completion Date: December 2, 2004
Report No.: 8567-04

Testing Laboratory: STILLMEADOW, Inc.
Author: Janice O. Kuhn, Ph.D., DABT

Quality Assurance (40 CFR §160.12): A Quality Assurance statement was included stating that an in-life inspection was not done and that the study outcome was not affected. A statement of Good Laboratory Practice (GLP) compliance was also included stating that the study meets the requirements of 40 CFR Part 160 and 792 and OECD specifications.

Test Material: SWAT 200 9B / Lot # CI-34-51 / clear, colorless liquid
Dosage: Limit Test: 5000 mg/kg (administered as received)

Species: 3 Sprague-Dawley albino rats
Sex: Female; nulliparous and nonpregnant
Age: Young adult (approximately 8 weeks)
Weight: 162 - 175 g (fasted weight on dosing day)
Source: Texas Animal Specialties, Humble, TX
Housing: Temperature Range: 20 - 22 °C
Relative Humidity: 55 - 100 %
Photoperiod: 12-hour light/dark cycle
Acclimation: 5 days

Conclusion:

1. **LD_{50} (mg/kg):** Females > 5000 mg/kg

2. **Tox. Category**: IV **Classification**:

Procedure (Deviations from §81-1): Upper value of humidity of animal housing was above protocol limits, however the laboratory states that this deviation did not affect study outcome. Rationale for initial dose level selection was not provided.

Results: No mortality occurred during the study.

Limit Test - Reported Mortality

Dose Level (mg/kg)	No. Dead / No. Dosed (Females)
5000	0 / 3

Observations: All animals appeared normal for the duration of the study. Body weight gain was noted for all animals during the test period.

Gross Necropsy Findings: The gross necropsy conducted at termination of the study revealed no observable abnormalities.

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (§81-2, 870.1200)
(LIMIT TEST)

Product Manager: Robert Brennis
MRID No.: 464411-08

Reviewer: Karen Hicks
Study Completion Date: December 15, 2004
Report No.: 8568-04

Testing Laboratory: STILLMEADOW, Inc.
Author: Janice O. Kuhn, Ph.D., DABT

Quality Assurance (40 CFR §160.12): A Quality Assurance statement was provided. A statement of Good Laboratory Practice (GLP) compliance was also included stating that the study meets the requirements of 40 CFR Part 160 and 792 and OECD specifications.

Test Material: SWAT 200 9B / Lot # CI-34-51 / clear, colorless liquid

Species:	New Zealand White Albino rabbits
	(5 / sex; females were nulliparous and nonpregnant)
Age:	Young Adult (approximately 12 weeks)
Weight:	Males: 2.600 - 3.050 kg
	Females: 2.300 - 3.000 kg
Source:	Nichols Rabbitry Inc., Lumberton, TX
Housing:	Temperature Range: 19 - 21 °C
	Relative Humidity: 67 - 100 %
	Photoperiod: 12-hour light / 12-hour dark cycle
Acclimation:	5 days

Summary:

1. **LD_{50} (mg/kg):** Males > 5050 mg/kg
   Females > 5050 mg/kg
   Combined > 5050 mg/kg

2. **The estimated LD_{50} is** > 5050 mg/kg

3. **Tox. Category:** IV **Classification:**

Procedure (Deviations From §81-4): The upper humidity level was above the range specified in the guidelines. The laboratory states, however, that the high humidity deviation did not affect study outcome, and that there were no deviations from the protocol that affected the quality or outcome of the study.

Results: No mortality occurred during the study.

Reported Mortality

DOSAGE (mg/kg)	DEATHS / number tested		
	Males	Females	Total
5050	0 / 5	0 / 5	0 / 10

Observations: All animals exceeded their initial body weight by study termination (Day 14). All animals appeared normal for the duration of the study. There were no signs of dermal irritation in any animals during the study.

Gross necropsy findings: The gross necropsy conducted at termination of the study revealed no observable abnormalities, except discolored lungs in one male and two females.

DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (§81-3, 870.1300)
LIMIT TEST

Product Manager: Robert Brennis
MRID No.: 464411-09

Reviewer: Karen Hicks
Study Completion Date: December 10, 2004
Report No.: 8569-04

Testing Laboratory: STILLMEADOW, Inc.
Author: Lori Carter, B.A.

Quality Assurance (40 CFR §160.12): A Quality Assurance Statement was provided. A statement of Good Laboratory Practice (GLP) compliance was also included stating that the study was conducted in compliance with 40 CFR Part 160 and 792 and OECD specifications.

Test Material: SWAT 200 9B / Lot # CI-34-51 / clear, colorless liquid

Species: 10 Sprague-Dawley rats
(5 / sex; females - nulliparous and nonpregnant)
Age: Young adult (approximately 8 weeks)
Weight: Males: 271 - 317 grams on the day after receipt
Females: 199 - 212 grams on the day after receipt
Housing: Temperature Range: 20 - 22 °C
Relative Humidity: 56 - 100 %
Photoperiod: 12-hour light/dark cycle
Acclimation: 5 days
Source: Texas Animal Specialities, Humble, TX

Concentration:

Group	Gravimetric Exposure Concentration (mg/L)	Nominal Concentration (mg/L)
I	2.19	2.61

The exposure was conducted in a 500 L nose-only stainless steel inhalation chamber. The test atmosphere concentration in the breathing zone of the rats was determined once per hour during the four-hour exposure period and nominally at the end of the exposure.

Summary:

1. **LC_{50} (mg/L) 4-hr exposure:** Males > 2.19 mg/L
   Females > 2.19 mg/L
   Combined >2.19 mg/L
2. **The estimated LC_{50} is > 2.19 mg/L**
3. **MMAD**: 2.5 µm
4. **Tox. Category**: IV **Classification**:

Procedure (Deviation From §81-3): The upper level of humidity of animal housing was above the humidity range as set by the guidelines, however, the laboratory states that the high humidity did not affect study outcome. Temperature of exposure chamber during the study was below the protocol parameters. The laboratory states that this did not affect study outcome, and that there were no deviations from the protocol which affected the quality or outcome of the study.

Results:

Reported Mortality

Exposure Concentration (mg/L)	Number of deaths / number tested		
	Males	Females	Combined
2.19	0 / 5	0 / 5	0 / 10

Chamber Atmosphere

Expos. Conc. (mg/m^3)	MMAD (mm)	GSD (mm)	% Particles							
			< 18.4	< 11.0	< 4.4	<2.7	< 1.7	< 1.0	< 0.5	< 0.3
2.19	2.2	4.3	96.55	93.10	55.17	17.24	17.24	17.24	3.45	0.00
	2.8	3.9	97.87	76.60	53.19	12.77	4.26	2.13	0.00	0.00

Chamber Environment During Exposure

Exposure Level	2.19 mg/L
Chamber Volume	500 L
Airflow	195 lpm
Temperature	65 °F
Relative Humidity	68 %

Clinical Observations: There were no mortalities during the study. Body weight gain was unaffected by administration of the test substance, except in one female that lost weight between Days 0 and 7. Prominent in-life observations included activity decrease and piloerection in both sexes. Animals were asymptomatic by Day 3.

Gross Necropsy Findings: The gross necropsy conducted on each animal at termination of the study revealed no observable abnormalities.

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (§81-4, 870.2400)

Product Manager: Robert Brennis
MRID No.: 464411-10

Reviewer: Karen Hicks
Study Completion Date: December 2, 2004
Report No.: 8570-04

Testing Laboratory: STILLMEADOW, Inc.
Author: Janice O. Kuhn, Ph.D., DABT

Quality Assurance (40 CFR §160.12): A Quality Assurance statement was provided. A statement of Good Laboratory Practice (GLP) compliance was also included stating that the study meets the requirements of 40 CFR Part 160 and 792 and OECD specifications.

Test Material: SWAT 200 9B, Lot # CI-34-51, clear, colorless liquid
Dosage: 0.1 mL - undiluted

Species: New Zealand White rabbits
Sex: 2 Male; 1 Female
Age: Approximately 12 weeks
Source: Nichols Rabbitry Inc., Lumberton, TX
Housing: Temperature Range: 19 - 21 °C
Relative Humidity: 73 - 100 %
Photoperiod: 12-hour light / 12-hour dark cycle

Summary:

1. **Toxicity Category**: IV

2. **Classification**:

Procedure (Deviations From §81-4): The upper level of humidity of animal housing was above that specified by the guidelines. The laboratory states, however, that the high humidity did not affect the study outcome and that there were no deviations from the protocol which affected the quality or outcome of the study.

The pH of the test substance was determined to be 12.2, however, the test was conducted and the test substance was rated minimally irritating.

Results:
There were no "positive" effects exhibited in any eyes at any time during the study.

Incidence of Irritation

Time Post Instillation	Corneal Opacity	Iritis	Conjuctivitis
1 hour	0 / 3	0 / 3	0 / 3
24 hours	0 / 3	0 / 3	0 / 3
48 hours	0 / 3	0 / 3	0 / 3
72 hours	0 / 3	0 / 3	0 / 3

Individual Ocular Irritation Scores

Observations	Rabbit No.: 7890-M (Male)				Rabbit No.: 7892-M (Male)				Rabbit No.: 7897-F (Female)			
	Hours				Hours				Hours			
	1	24	48	72	1	24	48	72	1	24	48	72
I. Corneal Opacity	+	+	0	0	+	0	0	0	0	0	0	0
II. Iritis	0	0	0	0	0	0	0	0	0	0	0	0
III. Conjunctivae:												
A. Redness	0	0	0	0	1	0	0	0	0	1	0	0
B. Chemosis	0	0	0	0	0	0	0	0	0	0	0	0
C. Discharge	1	0	0	0	1	0	0	0	0	0	0	0

Any corneal involvement or iridic irritation with a score of 1 or more is considered positive. Any conjunctival irritation (redness or chemosis) with a score of 2 or more is considered positive.

DATA REVIEW FOR DERMAL IRRITATION TESTING (§81-5, 870.2500)

Product Manager: Robert Brennis
MRID No.: 464411-11

Reviewer: Karen Hicks
Study Completion Date: December 2, 2004
Report No.: 8571-04

Testing Laboratory: STILLMEADOW, Inc.
Author: Janice O. Kuhn, Ph.D., DABT

Quality Assurance (40 CFR §160.12): A Qualtiy Assurance statement was provided. A statement of Good Laboratory Practice (GLP) compliance was also included, stating that the study meets the requirements of 40 CFR Part 160 and 792 and OECD specifications.

Test Material: SWAT 200 9B / Lot # CI-34-51 / clear, colorless liquid
Dosage: 0.5 mL - undiluted

Species: New Zealand White Albino rabbits
Sex: 1 Male; 2 Females
Age: Approximately 12 weeks
Source: Nichols Rabbitry Inc., Lumberton, TX
Housing: Temperature: 18 - 21 °C
Humidity: 77 - 100 %
Photoperiod: 12-hour light / 12-hour dark cycle

Summary:

1. **Toxicity Category**: IV

2. **Classification**:

Procedure (Deviations From §81-4): The laboratory states that the high humidity did not affect study outcome and that there were no deviations from the protocol which affected the quality or outcome of the study.

The pH of the test substance was determined to be 12.2, however, the study was conducted and the test material was given a descriptive rating of non-irritating.

Results: Erythema and edema were not observed at any time throughout the study. No other signs of irritation were observed during the study.

Incidence of Irritation

Time after Patch Removal	Erythema	Edema
1 hour	0 / 3	0 / 3
24 hours	0 / 3	0 / 3
48 hours	0 / 3	0 / 3
72 hours	0 / 3	0 / 3

DATA REVIEW FOR DERMAL SENSITIZATION TESTING (§81-6, 870.2600)
MODIFIED BUEHLER METHOD

Product Manager: Robert Brennis
MRID No.: 464411-12

Reviewer: Karen Hicks
Study Completion Date: December 15, 2004
Report No.: 8572-04

Testing Laboratory: STILLMEADOW, Inc.
Author: Janice O. Kuhn, Ph.D., DABT

Quality Assurance (40 CFR §160.12): A Quality Assurance statement was included. A statement of Good Laboratory Practice (GLP) compliance also included stating that the study meets the requirements of 40 CFR Part 160 and 792 and OECD specifications.

Test Material: SWAT 200 9B / Lot # CI-34-51 / clear, colorless liquid
Positive Control Material: 1-chloro-2,4-dinitrobenzene (DNCB)

Species:	34 Hartley-Albino guinea pigs
Sex:	17 Male and 17 Female
Age:	Aapproximately 5 weeks
Weight:	Males: 302 - 380 grams
	Females: 291 - 364 grams
Source:	Charles River Laboratories, Wilmington, MA
Housing:	Temperature Range: 20 - 24 °C
	Relative Humidity: 26 - 92 %
	Photoperiod: 12-hour light / 12-hour dark cycle
Acclimation:	5 days

Method: Modified Buehler Design

Summary:

1. **Based on the results of this study, SWAT 200 9B did not elicit a sensitization reaction in guinea pigs.**

2. **Classification**:

Procedure (Deviation From §81-6): The upper temperature level and both the lower and upper levels of relative humidity of animal housing were outside protocol limits. The laboratory states, however, that this did not affect the study outcome and that there were no deviations from the protocol that affected the quality or outcome of the study.

It is not indicated whether the females were nulliparous and nonpregnant.

Procedure:

Preparation and Observation of animals: Males and females were selected for each of two treatment groups. Group I animals (5/sex) served as a naive control group and Group II animals (10/sex) served as the test group. On the day prior to each treatment, the animals were prepared by clipping the back of the trunk free of hair to expose a longitudinal area of at least 8x10 cm on each animal. Individual body weights were recorded on Days 0 and 28. Observations for skin reactions at each test site were made approximately 24 hours after each treatment. In addition, observations for skin reactions were made approximately 48 hours after the first induction treatment and 48 hours after the challenge treatment.

Preliminary Irritation: Two male and two female albino guinea pigs were selected for irritation screening to determine both the maximum dose producing no more than moderate irritation, and the maximum non-irritating dose. Concentrations tested in the screening were 100 % (undiluted), and 75%, 50%, and 25% v/v dilution in deionized water, with each animal receiving 0.4 mL of each concentration at different test sites.

Induction Phase: For each induction treatment, Group II animals were treated by introducing the test substance beneath a 4-ply, 2.5 x 2.5 cm surgical gauze patch. Each gauze patch was placed laterally from the midline of the back on the left front quadrant of the exposure area and secured with a strip of non-irritating adhesive tape. A strip of clear polyethylene film was placed over the patch and securely taped. At the end of the 6-hour exposure period, the wrappings and patches were removed. Group II animals were treated once weekly for three weeks with 0.4 mL of the undiluted test substance. Induction treatments were on Days 1, 8 and 15. The same treatment regimen and test site location was used for all three induction treatments. Group I animals remained untreated during the induction phase of the study.

Challenge Phase: After a 2-week rest period, all animals (Groups I and II) were challenged at a virgin test site with a 0.4 mL application of the undiluted test substance. The dose was applied in a manner identical to the induction treatments, except the test site was placed laterally on the right rear quadrant of the exposure area.

Results: The test substance, SWAT 200 9B Lot CI-24-51, produced no irritation in the naive control animals (Group I) after the single treatment at challenge. The test substance likewise produced no irritation in the test animals (Group II) after the challenge treatment and therefore did not elicit a sensitizing reaction in guinea pigs.

Individual Challenge Data

	Dermal Scores	
	Hours	
	24	48
Test Animals	0 / 20	0 / 20
Naive Control Animals	0 / 10	0 / 10